DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 13, 2015

Sion Biotext Medical, Limited
c/o Ms. Tali Hazan
Talmed Ltd.
M.P Upper Galilee
Ramont Naftali, Ha Zafon 1383000
Israel

Re: K142473
Trade/Device Name: Lubricating Jelly
Regulation Number: 21 CFR 880.6375
Regulation Name: Patient Lubricant
Regulatory Class: I
Product Code: KMJ
Dated: March 5, 2015
Received: March 11, 2015

Dear Ms. Hazan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Sion Biotext
Medical Ltd.
Hagoshrim, 12225, ISRAEL. www.sb-medical.com
Tel: 972-4-6956201, Fax: 972-4-6956202 E-mail:sbmedical@sb-medical.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K142473

Device Name
Lubricating Jelly

Indications for Use *(Describe)*
The Lubricating Jelly is a medical device intended for medical purposes, to lubricate body orifices to facilitate entry of diagnostic or therapeutic devices when either sterile or non-sterile fields are required.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Mary E. Brooks -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary E. Brooks -S, 0.9.2342.19200300.100.1.1=1300372349
Date: 2015.04.01 15:09:43 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (1/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

Sion Biotext Medical Ltd.
Hagoshrim, 12225, ISRAEL. www.sb-medical.com
Tel: 972-4-6956201, Fax: 972-4-6956202 E-mail:sbmedical@sb-medical.com

510(K) SUMMARY FOR SION BIOTEXT MEDICAL'S LUBRICATING JELLY Device

DATE PREPARED: JULY 25, 2014

K142473

1. 510(K) OWNER NAME

Sion Biotext Medical Ltd.
Kibbutz Hagoshrim
Upper Galilee
Zip Code: 12225, Israel
Phone: +972-4-6956201, Fax: +972-4-6956202, E-mail: sbmedical@sb-medical.com.

Contact person:
Ms. Tali Hazan – RA Consultant
Phone: +972-(0)50-5292-304
Fax: +972-(0)722448981
Email: tali.hazan@talmed.co.il

2. DEVICE NAME AND CLASSIFICATION

Common/Usual Name: Lubricating Jelly (Sterile or Non-Sterile)
Proprietary/Trade name: *Lubricating Jelly*
Classification: Sion Biotext Medical's *Lubricating Jelly* device has been classified as **Class I** device under the following classification names:

Classification Name	Product Code	21 CFR Ref.	Review Panel
Lubricant, Patient	KMJ	880.6375	General Hospital

Sion Biotext Medical Ltd.
Hagoshrim, 12225, ISRAEL. www.sb-medical.com
Tel: 972-4-6956201, Fax: 972-4-6956202 E-mail:sbmedical@sb-medical.com

3. PREDICATE DEVICE

Sion Biotext Medical's *Lubricating Jelly* device is substantially equivalent to the following Predicate Device:

Dynarex Sterile Lubricating Jelly (by Dynarex Corporation) cleared under 510(k) number **K092488** on December 18, 2009.

4. DEVICE DESCRIPTION

Sion's *Lubricating Jelly* is used to lubricate body orifices to facilitate entry of diagnostic or therapeutic devices when either sterile or non-sterile fields are required. Typical uses of the lubricating jelly include (but not limited) insertion of catheters, endoscopes surgical instruments, gynecological, rectal, oral and rubber or plastic etc. The lubricating jelly is clear, greaseless, odorless, water soluble and non-irritating to the skin, tissue and mucous membranes.
Both product types (sterile and non-sterile) are packed in a bacterial barrier tubes or sealed laminated sachets.

Sion's *Lubricating Jelly* is a body contact material and was evaluated for biocompatibility with accordance to *FDA's Memorandum – #G95 1, May 1, 1995* and *ISO 10993-1:2009.*

5. INTENDED USE

The *Lubricating Jelly* is a medical device intended for medical purposes, to lubricate body orifices to facilitate entry of diagnostic or therapeutic devices when either sterile or non-sterile fields are required.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The *Lubricating jelly* is composed of water, carbomer thickeners, methylparaben, propylparaben, sodium hydroxide and lubricator. These ingredients are the same as those used for the predicate device and formulation is nearly the same.
Sion's *Lubricating jelly* is substantially equivalence to the predicate since it has the very same indication for use; it performs the same and has the same properties and labeling claims. It is intended to be used for the same patients' population.

The only differences between Sion's proposed device and Dynarex cleared device are that Sion provides the device as both 'sterile' and 'non-sterile' while Dynarex provides the product in sterile state only. Minor changes in the formulation were assessed and they do not affect the final device substantial equivalency determination.

7. PERFORMANCE DATA

Sion's *Lubricating Jelly* has been successfully tested for physical non-clinical performances' tests. These non-clinical testing data performed to evaluate device performances:

No.	Test Name	Per Standard
1.	**Chemical and Microbiological along Shelf Life:**	
1.1	Appearance	Specification
1.2	Weight	Specification
1.3	pH	Specification
1.4	Viscosity	Specification
1.5	Sterility and GPT	ISO 11737-2, USP <71>
1.6	Preservative Effectiveness	USP <51>
1.7	Dye Test	ASTM 1929
2.	**Biocompatibility:**	10993-1 (General)
2.1	Cytotoxicity	10993-5
2.2	Sensitization	10993-10
2.3	Irritation – Mucosal (Vaginal)	10993-10
2.4	Acute Systemic Toxicity	10993-11
3.	**Gammy Sterilization Validation**	ISO 11137-2, AAMI TIR 33
4.	**Sterile Packaging Integrity**	ISO 11607-1

All tested devices met the tests' requirements and pre-defined acceptance criteria. Therefore it was concluded that under normal use, the device will performed according to its specifications and intended uses.

Performance tests' results supported Sion's labeling claims and the determination of substantial equivalence with predicate device.

8. SUBSTANTIAL EQUIVALENCE

Sion's *Lubricating Jelly* is substantially equivalent to the predicate device selected in terms of indication for use, technology, performances, physical characterization, sterile product's sterility method, method of use, target patient population and nature of body contact.

9. CONCLUSIONS

As above described, the evaluation of our device performances demonstrates that it is equivalent and as safe and as effective as the predicate device.